

REMARKS

I. Claim Status

Reconsideration of the present application is respectfully requested. Claims 1-5, 7-10, 12, 16, 19, 20, 22 and 33 are pending. Claims 6, 11, 13, 14, 15, 17, 18, 21, 23-32 and 34 are canceled without prejudice. Claims 1 and 33 have been amended to more clearly describe the claimed invention, and are supported by the specification and claims as originally filed, for example, at page 9, paragraph 29; page 18, paragraph 45; and original claims 13 and 34. No new matter has been added by way of these amendments.

II. Rejection Under 35 U.S.C. § 112

Claims 16 stands rejected as unpatentable under 35 U.S.C. § 112, second paragraph, as indefinite. According to the Examiner, the claim lacks antecedent basis for reciting “the quaternary ammonium compound” in claim 1. Applicants submit that claim 1 has been amended to recite a composition comprising a quaternary ammonium compound, and as such, claim 16 has proper antecedent basis for the allegedly indefinite terms. Accordingly, Applicants respectfully request that the rejection be withdrawn.

III. Double Patenting

Claims 1, 2, 3, 5, 7-10, 12, 13, 16, 19, 20, and 22 stand provisionally rejected for nonstatutory obviousness-type double patenting over claims 1, 3-11, and 17 of co-pending application serial no. 10/622,272 (hereafter “the ‘272 application”). According to the Examiner, it would have been obvious to combine the ingredients noted in the ‘272 application to arrive at the presently claimed invention.

Since the rejection is provisional because the allegedly overlapping claims have not yet been patented, to the extent that claim scope overlaps in any patented case, Applicants respectfully submit that the appropriate action will be taken as the Examiner indicates allowable subject matter with regard to the pending rejections under 35 U.S.C. §§ 103(a) and 112.

IV. Rejections Under 35 U.S.C. § 103(a)

U.S. Patent No. 5,965,610 to Modak et al. in view of U.S. Patent No. 5,736,574 to Burnier et al.

Claims 1-3, 5, 7, 9, 19, 20, 22, 33 and 34 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,965,610 to Modak et al. (hereafter “Modak”) in view of U.S. Patent No. 5,736,574 to Burnier et al. (hereafter “Burnier”). The Examiner contends that Modak discloses a topical gel composition comprising zinc gluconate, a solvent (*i.e.*, water or alcohol), a thickening agent, a hydrophobic polymer, an emulsifying agent, an emollient, an antioxidant and an antimicrobial as encompassed by the pending claims. The Examiner further alleges that Burnier discloses synergistic antimicrobial combinations comprising N-n-octanoglycine and octoxyglycerin which are suitable for a wide variety of pharmaceutical and cosmetic compositions. According to the Examiner, it would have been obvious to one of ordinary skill in the art to combine the antimicrobial mixtures of Burnier with the composition of Modak, which allegedly describes the claimed invention.

Applicants respectfully disagree. To support an assertion of obviousness, the Examiner must show that “all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art.” M.P.E.P. § 2143. *See also KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

Claims 1 and 33 have been amended to recite a composition comprising a quaternary ammonium compound as an antimicrobial agent, and a method for preparing the same. Applicants submit that the claims as amended are not obvious over the cited references because an artisan of ordinary skill, in view of Modak and Burnier, would have no expectation of successfully practicing the claimed invention by combining the elements recited by the references.

Applicants submit that Burnier describes a “combinatory immixture of at least one compound exhibiting antimicrobial activity, selected from among the hydrolipids or lipids, and at least one glyceryl monoalkyl ether, [which] manifests a synergistic effect with regard to the antimicrobial activity of the combination.” *See Burnier* at Col. 1, ll. 40-47. Furthermore, Burnier discloses that such hydrolipids are “products resulting from the coupling of fatty acids

with hydrophilic molecules selected from among amino acids (monomers, peptides or proteins) and polysaccharides,” and that lipids are “branched or unbranched, saturated or unsaturated fatty acids.” *See* Burnier at Col. 2, ll. 12-16; and Col. 3, ll. 11-12. Burnier does not suggest or describe that a glyceryl monoalkyl ether can be combined with a quaternary ammonium chloride, as recited by the amended claims, or any other antimicrobial agent other than a hydrolipid or lipid to achieve an antimicrobially synergistic effect.

Additionally, Applicants note that Modak does not suggest or describe antimicrobial compositions comprising Burnier’s hydrolipid and lipid antimicrobials, nor does it suggest or describe that such antimicrobials can be successfully combined with zinc gluconate and the other ingredients disclosed by Modak to rapidly inactivate irritants while simultaneously being inhibited from binding a surface. While Modak discloses that antimicrobial agents may be combined with an anti-microbial synergist to achieve a greater antimicrobial effect, the reference does not disclose that a glyceryl monoalkyl ether or octoxyglycerin may be used as such a synergist. Furthermore, Modak suggests that compounds which can be successfully used as an anti-microbial synergist is dependent upon the antimicrobial agent present in a composition:

Examples of anti-microbial synergists which may be used with an anti-microbial agent when the anti-microbial agent is chlorhexidine or a pharmaceutically acceptable chlorhexidine salt include, but are not limited to, phenoxyethanol, phenylethyl alcohol, ethylene diamine tetraacetic acid, benzalkonium chloride, didecyltrimethylammonium chloride, a polyethyleneoxide surfactant, interferon, lipase, protease, and glucosidase.

See Modak at Col. 9, ll. 23-30. Thus, even if Modak did disclose that hydrolipids and lipids can be used as an antimicrobial compound in the formulations contemplated by the reference, which applicants do not concede, Modak provides a skilled artisan with no guidance as to which agents, if any, could be used as an anti-microbial synergist for such compounds.

Similarly, Burnier only discloses that hydrolipids and lipids may be combined with a glyceryl monoalkyl ether to achieve an antimicrobially synergistic effect. *See, e.g.*, Burnier at Col. 1, ll. 40-47; and the abstract. Burnier does not suggest or describe that glyceryl monoalkyl ethers can interact synergistically with a quaternary ammonium compound or any other antimicrobial agents. Thus, an artisan or ordinary skill, without knowledge of the instant application, would have no expectation that octoxyglycerin and a quaternary ammonium

compound could be combined to achieve a antimicrobially synergistic effect, as recited by the claims.

Applicants also assert that while there are limited circumstances where an obviousness rejection may fairly be based on a contention that the invention was obvious to try, the instant rejection does not fall within those limited circumstances. As noted by the Supreme Court in *KSR v. Teleflex*, 127 S.Ct. 1727, 1739 (2007), it is inappropriate to employ an obvious to try argument in situations where the outcome cannot be reasonably predicted. See, *KSR v. Teleflex*, 127 S.Ct. 1727, 1739 (2007). This distinction between predictable situations where an obvious to try argument is appropriate and unpredictable situations where an obvious to try argument is an inappropriate basis for obviousness was recently clarified further by the Federal Circuit in *In re Kubin*, 561 F3d 1531 (Fed. Cir. 2009):

In [unpredictable] circumstances, where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness. The inverse of this proposition is succinctly encapsulated by the Supreme Court's statement in *KSR* that where a skilled artisan merely pursues "known options" from a "finite number of identified, predictable solutions," obviousness under § 103 arises.

In re Kubin, 561 F3d 1531, 1359 (Fed. Cir. 2009). In the present application, the claims as amended are directed to compositions which exhibit antimicrobially synergistic effects achieved by combining octoxyglycerin and a quaternary ammonium compound. Although an artisan of ordinary skill may have been aware that synergistic effects could be produced by combining hydrolipids or lipids and glyceryl monoalkyl ethers, as disclosed by Burnier and discussed above, the artisan, in view of the cited references, would have no way of predicting what other compounds could interact synergistically with any one of the vast number of available antimicrobials, such as a quaternary ammonium compound. Specifically, without knowledge of the instant application, in which Applicants demonstrate that octoxyglycerin and a quaternary ammonium compound are antimicrobially synergistic, the skilled artisan would not have expected or predicted that the two compounds could be combined to achieve such an effect.

Additionally, as discussed in the previously filed responses, Applicants also submit that the claims of the instant application are not obvious over the cited references because practicing the claimed invention produces surprising and unexpected results which a person of ordinary

skill in the art would not have predicted in view of the cited references. *See* M.P.E.P. § 716.02(a) and § 2143.02; *see also In re Papesch*, 315 F.2d 381 (C.C.P.A. 1963). Specifically, the antimicrobial synergy achieved by combining octoxyglycerin and a quaternary ammonium compound together in a single composition is a surprising and unexpected result indicative of the claims' non-obviousness over the cited references. *See* M.P.E.P. § 716.02(a). For example, as disclosed in Example 1 of the instant application (*see* pp. 34-36), compositions comprising either octoxyglycerol (*i.e.* Sensiva SC50) or benzalkonium chloride ("BZK") alone were ineffective against *S. aureus*, but when present together in a single composition, the composition exhibited a surprisingly strong and unexpected antimicrobially synergistic effect against *S. aureus*.

Tables 1 and 2 show that no significant antimicrobial activity against *S. aureus* was obtained with 2-5 percent [octoxyglycerol] . . . Similarly, 0.12 and 0.19 percent BZK exhibited minimal or no antimicrobial activity (Table 2). However, combinations of 1-2 percent Sensiva SC50 and 0.12-0.19 percent BZK showed 5000-33000 fold reduction in colony-forming units compared to control values (Table 2).

See the specification, Example 1, at p. 36, ¶60. Thus, an artisan of ordinary skill, in view of Burnier, which disclose that a glyceryl monoalkyl ether may only be combined with hydrolipids or lipids to achieve a synergistic effect, and Modak, which discloses that there are certain antimicrobial synergists for which a given antimicrobial agent will be responsive to, would not have predicted that octoxyglycerin and a quaternary ammonium compound could be combined to achieve antimicrobial synergy. The cited references do not suggest or describe that all antimicrobial synergists are effective for all antimicrobial agents, nor do the references suggest or describe that octoxyglycerin would be an effective synergist for any antimicrobial agent other than hydrolipids and lipids.

For the reasons described above, Applicants submit that a skilled artisan, in view of the cited references, would have no expectation of successfully practicing the claimed invention, and further, because practicing the claimed invention produces a surprising and unexpected synergistic antimicrobial effect, the claims are not obvious over Modak and Burnier. Applicants respectfully request that the rejection be withdrawn.


V. **Conclusion**

In view of the above amendments and remarks, it is respectfully requested that the application be allowed and passed to issue. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below. Applicants believe that no fee in addition to the fee associated with the Request for Continued Examination filed herewith, is due at this time. However, if any other fee is required, the Commissioner is authorized to charge such fee to Deposit Account No. 02-4377.

Respectfully submitted,

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